

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NO.
		1003301-000277
		U.S. APPLICATION NO. (If known)
		10/585,054
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/SE2005/000054	19 January 2005	04 February 2004
TITLE OF INVENTION		
DIUREA DERIVATIVES		
APPLICANT(S) FOR DO/EO/US		
ABRAMO, Aina Lisbeth, PETTERSSON, Lars Olof Goran, ANDERSSON, Kerstin Ingalill and SUNDSTEDT, Asa Anette		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> <p>Items 11 to 20 below concern document(s) or information included:</p> <ol style="list-style-type: none"> <li>11. <input checked="" type="checkbox"/> A SECOND Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input type="checkbox"/> A preliminary amendment.</li> <li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).</li> <li>20. <input type="checkbox"/> Other items or information: _____</li> </ol>		

U.S. APPLICATION NO. (If known) 10/585,054	INTERNATIONAL APPLICATION NO. PCT/SE2005/000054	ATTORNEY'S DOCKET NO. 1003301-000277
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The following fees have been submitted:				CALCULATIONS	PTO USE ONLY
21. <input type="checkbox"/>	Basic National fee (37 CFR 1.492(a)) (1631) \$ 300			\$ 0	
22. <input type="checkbox"/>	Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) (1643) \$ 0 All other situations (1633) \$ 200			\$ 0	
23. <input type="checkbox"/>	Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) (1640) \$ 0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority (1641) \$ 100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB (1642) \$ 400 All other situations (1632) \$ 500			\$ 0	
<b>TOTAL OF 21, 22 AND 23 =</b>				<b>\$ 0.00</b>	
<input type="checkbox"/>	Additional fee for specifications and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$ 250 (1681) for each additional 50 sheets of paper or fraction thereof.				
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
0	-100 = 0	/50 = 0	x \$ 250	\$ 0	
<input type="checkbox"/> Surcharge of \$ 130 (1617) for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	20	- 20 = 0	x \$ 50 (1615)	\$ 0	
Independent Claims	1	- 3 = 0	x \$ 200 (1614)	\$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 360 (1616)	\$ 0	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$ 0.00</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2				0	
<b>SUBTOTAL =</b>				<b>\$ 0.00</b>	
Processing fee of \$ 130 (1618) for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				0	
<b>TOTAL NATIONAL FEE =</b>				<b>\$ 0.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$ 40 per property				+	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$ 0.00</b>	
				<b>Amount to be refunded:</b>	<b>\$</b>
				<b>Amount to be charged:</b>	<b>\$</b>

a. ☐ A check in the amount of \_\_\_\_\_ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 02-4800 in the amount of \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.


c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-4800. A duplicate copy of this sheet is enclosed.

d. ☐ Charge \$130.00 to credit card. Form PTO-2038 is attached.

**NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.**

SEND ALL CORRESPONDENCE TO:

Customer No 21839  
P.O. Box 1404  
Alexandria, VA 22313-1404  
703 836 6620  
Date: September 25, 2006

  
SIGNATURE

Benton S. Duffett, Jr. 22030  
NAME REGISTRATION NO.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	MAIL STOP PCT
Aina Lisbeth ABRAMO et al.	)	Attention: DO/EO/US
Application No.: 10/585,054	)	Group Art Unit: Unassigned
Filing Date: June 30, 2006	)	Examiner: Unassigned
Title: DIUREA DERIVATIVES	)	Confirmation No.: Unassigned
	)	

**SECOND  
INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:


Enclosed is a SECOND Information Disclosure Statement (IDS) and accompanying form PTO-1449 for the above-identified patent application.

- ☐ No additional fee for submission of an IDS is required.
- ☐ The fee of \$ 180 as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$ 180 as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the fee due.
- ☐ Charge \_\_\_\_\_ to credit card for the fee due. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date September 25, 2006

By:   
Benton S. Duffett, Jr.  
Registration No. 22030

P.O. Box 1404  
Alexandria, VA 22313-1404  
703 836 6620

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	<b>MAIL STOP PCT</b>
	)	
Aina Lisbeth ABRAMO et al.	)	<b>Attention: DO/EO/US</b>
	)	
Application No.: 10/585,054	)	Group Art Unit: Unassigned
	)	
Filed: June 30, 2006	)	Examiner: Unassigned
	)	
For: DIUREA DERIVATIVES	)	Confirmation No.: Unassigned

**SECOND INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

This will supplement the earlier Information Disclosure Statement filed on June 30, 2006.

Copies of the following publications that are identified in Applicants' Specification at Pages 40 and 41 are provided.

- (1) Abbas, Abul K. et al., *Nature*, Volume 383, October 31, 1996, Pages 787-793, "Functional Diversity of Helper T Lymphocytes".
- (2) Blessing, Jack J.H., *Current Pharmaceutical Design*, Volume 9, 2003, Pages 265-278, "Autoimmune Lymphoproliferative Syndrome (ALPS)".
- (3) Eguchi, Katsumi, *Internal Medicine*, Volume 40, No. 4, April 2001, Pages 275-284, "Apoptosis In Autoimmune Diseases".
- (4) Sacca, Rosalba, et al., *Current Opinion in Immunology*, Volume 9, 1997, Pages 851-857, "Mediators of Inflammation".
- (5) Tang, Dean G. et al., *Pathology Oncology Research*, Volume 2, No. 3, 1996, Pages 117-131, "Apoptosis: A Current Molecular Analysis".

- (6) Van Engeland, Manon et al., *Cytometry*, Volume 31, 1998, Pages 1-9, "Annexin V-Affinity Assay: A Review on an Apoptosis Detection System Based On Phosphatidylserine Exposure".
- (7) Waldmann, Thomas A., *Immunology Today*, Volume 14, No. 6, 1993, Pages 264-270, "The IL-2/IL-2 Receptor System: A Target for Rational Immune Intervention".
- (8) Waldmann, Thomas A. et al., *Immunology*, Volume 14, February 2001, Pages 105-110, "Contrasting Roles of IL-2 and IL-15 in the Life and Death of Lymphocytes: Implications for Immunotherapy".
- (9) Willingham, Mark C., *The Journal of Histochemistry and Cytochemistry*, Volume 47(9), 1999, Pages 1101-1109, "Cytochemical Methods for the Detection of Apoptosis".
- (10) White, A.K. et al., *Leukemia*, Volume 15, 2001, Pages 1011-1021, "Suppression of Apoptosis: Role in Cell Growth and Neoplasia".

A copy of Aulton, M.E., *Pharmaceutics*, 1988, 678 pages, "The Science of Dosage Form Design", Churchill Livingstone (ISBN:0443055173), which is identified at Page 40 of the Specification is not being provided with this submission since it constitutes an entire book. However, should the Examiner desire to inspect this and lacks access to a copy of the book, please notify the undersigned attorney and an effort will be made to acquire and to supply the book for the convenience of the Examiner.

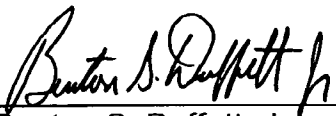
To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: September 25, 2006

By: \_\_\_\_\_

  
Benton S. Duffett, Jr.  
Registration No. 22030

P.O. Box 1404  
Alexandria, VA 22313-1404  
703 836 6620

**SECOND  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(use as many sheets as necessary)

Sheet 1 of 1

Application Number	10/585,054
Filing Date	June 30, 2006
First Named Inventor	Aina Lisbeth Abramo et al.
Examiner Name	Unassigned
Attorney Docket No.	1003301-000277

**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	STATUS						
					Translation	Partial Translation	Eng. Lang. Summary	Search Report	IPER	Abstract	Cited in Spec

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Abbas, Abul K. et al., <i>Nature</i> , Volume 383, October 31, 1996, Pages 787-793, "Functional Diversity of Helper T Lymphocytes".
	Blessing, Jack J.H., <i>Current Pharmaceutical Design</i> , Volume 9, 2003, Pages 265-278, Autoimmune Lymphoproliferative Syndrome (ALPS).
	Eguchi, Katsumi, <i>Internal Medicine</i> , Volume 40, No. 4, April 2001, Pages 275-284, "Apoptosis In Autoimmune Diseases".
	Sacca, Rosalba, et al., <i>Current Opinion in Immunology</i> , Volume 9, 1997, Pages 851-857, "Mediators of Inflammation".
	Tang, Dean G. et al., <i>Pathology Oncology Research</i> , Volume 2, No. 3, 1996, Pages 117-131, "Apoptosis: A Current Molecular Analysis".
	Van Engeland, Manon et al., <i>Cytometry</i> , Volume 31, 1998, Pages 1-9, "Annexin V-Affinity Assay: A Review on an Apoptosis Detection System Based On Phosphatidylserine Exposure".
	Waldmann, Thomas A., <i>Immunology Today</i> , Volume 14, No. 6, 1993, Pages 264-270, "The IL-2/IL-2 Receptor System: A Target for Rational Immune Intervention".
	Waldmann, Thomas A. et al., <i>Immunology</i> , Volume 14, February 2001, Pages 105-110, "Contrasting Roles of IL-2 and IL-15 in the Life and Death of Lymphocytes: Implications for Immunotherapy".
	Willingham, Mark C., <i>The Journal of Histochemistry and Cytochemistry</i> , Volume 47(9), 1999, Pages 1101-1109, "Cytochemical Methods for the Detection of Apoptosis".
	White, A.K. et al., <i>Leukemia</i> , Volume 15, 2001, Pages 1011-1021, "Suppression of Apoptosis: Role in Cell Growth and Neoplasia".

Examiner Signature

/Peter O Sullivan/

Date Considered

01/29/2010

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.O./